K040030

JUN 16 2004

510(k) Summary

BioCheck, Inc.

CRP RAPID TEST

For the qualitative detection of C-reactive protein (CRP) in human serum.

I. MANUFACTURER:

BioCheck, Inc.
323 Vintage Park Drive
Foster City, CA 94404
Phone: (650) 573-1968
Fax: (650) 573-1969
Regulatory Contact: Hellen Professional Services
Phone: (818) 709-5646

II. DEVICE NAME and CLASSIFICATION:

Proprietary Name:	BioCheck Rapid C-Reactive Protein Test Kit
Catalog Number:	804114
Common Name:	BioCheck *CRP Rapid Test*
Classification Name:	C-reactive Protein Immunological Test System (866.5270)

III. INTENDED USE and ASSAY PRINCIPLE:

The *BioCheck CRP Rapid Test* is intended for the qualitative detection of C-reactive protein (CRP) in human serum. Measurements of CRP can be useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

The *BioCheck CRP Rapid Test* is a colloidal gold/antibody conjugate-based immunoassay designed for the detection of CRP in human serum samples. To perform the serum CRP test, serum is dispensed into the sample well. CRP that is present in the specimen is bound by a gold-antibody conjugate forming a gold-antibody-antigen complex. This complex migrates across the membrane by capillary action and reacts with a goat anti-human CRP polyclonal antibody immobilized in the test region to produce a pink color band when the CRP concentration is equal to or greater than **4.0 mg/L**. If CRP concentration is less than 4.0 mg/L in the specimen, there is no line in the test line area. The mixture continues to migrate to the control line area and produce a pink color band, indicating a valid test.

IV. SUBSTANTIAL EQUIVALENCE:

The *BioCheck CRP Rapid Test* is substantially equivalent to the BioCheck hsCRP ELISA currently manufactured by BioCheck, Inc., Foster City, CA 94404. Both assays are used for the qualitative or quantitative (BioCheck ELISA) detection of CRP in human serum.

V. TEST PERFORMANCE:

1. *Precision*

Four laboratories were provided with blind serum samples that had been spiked with purified CRP. Five samples containing 1.0, 2.0, 3.0, 4.0, and 8.0 mg/L CRP were prepared. Five blind replicates of each sample were tested in each site for a total of 25 tests per site. All samples were also tested in manufacture's laboratory. The assay results demonstrated 100% agreement in between run proficiency and 100% agreement between sites.

2. *Interference*

The following potentially interfering substances do not appear to interfere with the determination of CRP in the *BioCheck CRP Rapid Test* up to the levels indicated below:

Analyte	Test Level
Biotin	200 ng/mL
Bilirubin	10 mg/dL
Hemoglobin	200 mg/dL
Cholesterol	800 mg/dL
Triglyceride	1250 mg/dL

In vitro testing of the following common-used drugs revealed no interference within the normal therapeutic range:

Analyte (~10 µg/ml Final Concentration)		
Acetaminophen	Captopril	Isosorbide dinitrate
Acetylsalicylic acid	Chloramphenicol	Nifedipine
Adenine	Cinnarizine	Nystatin
Albumin (bovine)	Cyclophosphamide	Oxazepam
Allopurinol	Cyclosporine	Oxytetracycline
Ambroxol	Digitonin	Propranolol
Ampicillin	Digoxin	Theophylline
Ascorbic acid	Dopamine	L-thyroxine
Atenolol	Erythromycin	Urea
Atropine	Gentistic acid	Uric acid
Caffeine	Isoproterenol	

3. *Hook Effect*

When CRP standard of 200 mg/L was used for evaluation of hook effect, the test line appeared after 5 minutes. Thus, there is no hook effect if CRP concentration in patient serum sample is equal to or below 200 mg/L.

4. *Recovery Study*

Normal human serum was supplemented with purified human CRP to yield concentrations of 1.0, 4.0, and 8.0 mg/L. The dilutions were tested in six replicates using the *BioCheck CRP Rapid Test*. The data showed 100% agreement between the expected and the observed results at each CRP concentration.

V. TEST PERFORMANCE:

5. *Clinical Comparison*

A total of 384 patient serum samples from three separate testing groups were tested with the *BioCheck CRP Rapid Test* and compared with a commercially available quantitative assay for CRP (BioCheck hsCRP ELISA).

Group #1 compared both devices on randomly selected patient samples and Group #2 tested the two devices on patient samples with elevated CRP values. Lastly, Group #3 tested both devices on patients with known disease status (e.g., inflammation, infection).

Based on the clinical cutoff of 4.0 mg/l, the positive and negative agreement of the *BioCheck CRP Rapid Test* was compared to the BioCheck predicate device. Overall positive agreement (≥ 4 mg/L) was reported as 98.2%, while negative agreement (< 4 mg/L) was calculated at 96.3%. Individual agreements observed in each group were as follows:

- Group #1: Positive Agreement = 97.2%, Negative Agreement = 97.1%, Overall Accuracy = 97.1%.
- Group #2: Positive Agreement = 98.6%, Negative Agreement = 94.7%, Overall Accuracy = 96.6%.
- Group #3: Positive Agreement = 100%, Negative Agreement = 100%, Overall Accuracy = 100%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 6 2004

Biocheck, Inc.
c/o Robin J. Hellen, M.S.
Hellen Professional Services
9418 Lasaine Avenue
Northridge, CA 91325

Re: k040030
Trade/Device Name: BioCheck, Inc. CRP Rapid Test
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN
Dated: May 4, 2004
Received: May 10, 2004

Dear Ms. Hellen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

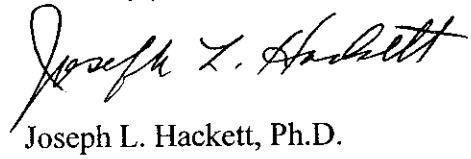
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

STATEMENT FOR INDICATIONS FOR USE

510(k) Number (if known): K040030

Device Name: *BioCheck, Inc. CRP Rapid Test*

Indications for Use:

The *BioCheck CRP Rapid Test* is intended for the qualitative detection of C-reactive protein (CRP) in human serum. Measurements of CRP can be useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over the Counter Use: _____

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040030